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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,631	04/16/2007	Stephen O'Hara	63162US005	5768

32692 7590 03/01/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
03/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/576,631	O'HARA, STEPHEN	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/7/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 12/7/09 has been entered into the record. Claims 1-9 and 12-19 are pending and are under examination.

Information Disclosure Statement

The information disclosure statement filed 12/7/09 has been considered and an initialed copy is enclosed.

Claim Rejections Withdrawn

1. The rejection of claims 1-10 and 13-15 under 35 U.S.C. 102(b) as being anticipated by Peck et al. US 5,789,173 Aug. 4 1998 is withdrawn in view of the amendment to the claims.

2. The rejection of claims 1-10, 12 and 13-15 under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998 is withdrawn in view of the amendment to the claims.

3. The rejection of claims 1-11 and 13-15 under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998 in view of Bruno et al. Journal of Molecular Recognition, Vol. 9, 474-479 (1996) cited in IDS is withdrawn in view of the amendment to the claims.

4. The rejection of claims 1-19 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment to the claims.

5. The rejection of claims 1, 2, 4, 5, 6, 7, 12-15, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Cooksey et al. Journal of Clinical Microbiology, May 2002, p. 1651-1655 is withdrawn in view of the amendment to the claims.

6. The rejection of claims 1-10 and 13-18 under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998 in view of Kohne et al. US 5,738,988 April. 14, 1998 is withdrawn in favor of a new rejection in view of the amendment to the claims. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on amendment to the claims. A new rejection over Peck and Kohne et al relying on a new combination of portions of the cited references necessitated by the instant amendments is set forth below.

7. The rejection of claims 1-9 and 12-19 under 35 U.S.C. 103(a) as being unpatentable over Cooksey et al. Journal of Clinical Microbiology, May 2002, p. 1651-1655 in view of Kohne et al. US 5,738,988 April. 14, 1998 is withdrawn in view of the amendment to the claims.

8. The rejection of claims 1-19 under 35 U.S.C. 103(a) as being unpatentable over Cooksey et al. Journal of Clinical Microbiology, May 2002, p. 1651-1655 and Kohne et al. US 5,738,988 April. 14, 1998, as applied to claims 1-9 and 12-19, further in view of Bruno et al. Journal of Molecular Recognition, Vol. 9, 474-479 (1996) cited in IDS is withdrawn in view of the amendment to the claims.

New Rejections Based on Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Claim 1 is drawn to a process for analyzing a biological sample containing two or more microorganisms, comprising the steps of:
(a) identifying two or more microorganisms present within the sample by analyzing the two or more microorganisms' nucleic acid; and
(b) determining, in parallel, the effect of one or more antimicrobial(s) on the two or more microorganisms from the sample, wherein determining the effect of one or more antimicrobials comprises adding an antimicrobial at a pre-determined concentration to the sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the two or more microorganisms, and assessing the number of each one of the two or more microorganisms in the sample at the end of the pre-determined time period by analyzing the microorganisms' nucleic acid; wherein steps (a) and (b) are performed by without prior separation of the two or more microorganisms.

Claim 18 as amended is drawn to the process of claim 1, wherein analyzing the microorganism's nucleic acid comprises determination of comparing at least a part of the microorganism's genome sequence to a known sequence.

Claim 19 as amended is drawn to the process of claim 1, wherein analyzing the microorganism's nucleic acid comprises restriction fragment length polymorphism analysis or amplified rDNA restriction analysis.

Claim 1 has two steps wherein analysis of nucleic acid occurs i.e. in step a (identifying two or more microorganisms present within the sample by analyzing the two or more microorganisms' nucleic acid…) and step b (determining, in parallel, the effect of one or more antimicrobial(s) on the two or more microorganisms from the sample… and assessing the

number of each one of the two or more microorganisms in the sample at the end of the pre-determined time period by analyzing the microorganisms' nucleic acid…).

Applicants state that support for claims 18 and 19 is at p. 2 lines 31-32 and p. 2 lines 34-36, respectively and stated below:

> p. 2 lines 31-32: Sequencing techniques involve the determination of at least part of a micro-organism's genome sequence. For example, the sequence of the gene encoding a bacteria's 16S rRNA can be determined and the micro-organism can be identified by checking that sequence against known sequences. The use of 16S sequencing for pathogen identification in the clinical laboratory is reviewed in ref. 21.
>
> p. 2 lines 34-36: Nucleic acid separation can be used to identify a micro-organism using techniques such as restriction fragment length polymorphism (RFLP) [22] or amplified rDNA restriction analysis (ARDRA) [23].

It is noted that the portion of the specification above, is drawn to only identification of the micro-organism but does not disclose using the methods of claim 18 and 19 for step b as claimed which recites "…assessing the number of each one of the two or more microorganisms in the sample at the end of the pre-determined time period by analyzing the microorganisms' nucleic acid…". The portion of the specification above does not support the use of the methods of claim 18 and 19 in "…assessing the number of each one of the two or more microorganisms in the sample at the end of the pre-determined time period by analyzing the microorganisms' nucleic acid…" as recited in step b.

Applicants may point to the specification for where supports for the method of claim 18 and 19 for "…assessing the number of each one of the two or more microorganisms in the sample at the end of the pre-determined time period by analyzing the microorganisms' nucleic acid…" as recited in step b in order to obviate the instant rejection or amend the claims to remove the new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-9 and 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of claim 1 is not clear because the claim recites that "…the effect of one or more antimicrobial(s) on the two or more microorganisms *from the sample…*" implying that the microorganisms are separated from the sample yet also recites that "…assessing the number of each one of the two or more microorganisms *in the sample…*"…"

and "… wherein steps (a) and (b) are performed without prior separation of the two or more microorganisms..." which implies that the microorganisms are not separated from the sample.

Furthermore, in claim 1 step (b) and dependent claims, it is not clear how the number of each one of the two or more microorganisms in the sample is assessed at the end of the pre-determined time period just by mere analysis of the microorganisms' nucleic acid including analyzing the microorganism's nucleic acid by comparing at least a part of the microorganism's genome sequence to a known sequence or by analyzing the microorganism's nucleic acid by restriction fragment length polymorphism analysis or amplified rDNA analysis. There is no linkage of analysis of the microorganisms' nucleic acid with assessment of numbers of each of the two or more microorganisms in the sample and analysis of the microorganisms' nucleic acid does not clearly convey how such analysis results in assessment of the number of each one of the two or more microorganisms in the sample.

Clarification of the claims is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3, 8-9 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998, cited previously in view of Kohne et al. US 5,738,988 April. 14, 1998, cited previously.

The previous rejection of Peck in view of Kohne is withdrawn (see above under "rejections withdrawn") in favor of a new rejection in view of the amendment to the claims. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on amendment to the claims. A new rejection over Peck and Kohne et al relying on a new combination of portions of the cited references necessitated by the instant amendments and addressing the newly amended claims is set forth below.

The claims are drawn to a process for analyzing a biological sample containing two or more microorganisms, comprising the steps of:
(a) identifying two or more microorganisms present within the sample by analyzing the two or more microorganisms' nucleic acid; and
(b) determining, in parallel, the effect of one or more antimicrobial(s) on the two or more microorganisms from the sample, wherein determining the effect of one or more antimicrobials comprises adding an antimicrobial at a pre-determined concentration to the sample, incubating the sample in the presence of the antimicrobial for a pre-determined time period under conditions that allow some growth of the two or more microorganisms, and assessing the number of each one of the two or more microorganisms in the sample at the end of the pre-determined time period by analyzing the microorganisms' nucleic acid; wherein steps (a) and (b) are performed by without prior separation of the two or more microorganisms.

Peck et al teaches a method for rapid antimicrobial susceptibility testing to screen antimicrobials including antibiotics achieved by a short period of specimen (biological sample) incubation in different antimicrobial/antibiotic embedded media to create differential microbial counts (e.g. of bacteria or fungi and pathogens in general) followed by DNA amplification (e.g. PCR) and rapid quantitation. See abstract and figure 1 "the innovation" and column 2 lines 24-35, 60-67 to column 3 lines 1-7, column 10 claim 1. Peck et al teaches that identification of the pathogen can be done in parallel by conventional methods. See column 2 lines 18-21.

Peck et al does not teach that the identification step involves the identification of two or more microorganisms present within the sample by analyzing the two or more microorganisms' nucleic acid and does not teach that the antimicrobial susceptibility testing involves determining the effect of one or more one or more antimicrobial(s) on two or more microorganisms from the sample and assessing the number of each one of the two or more microorganisms in the sample at the end of the pre-determined time (in the presence of the antimicrobial) period by analyzing the microorganisms' nucleic acid; wherein identification and the effect of antimicrobial on the two or more different microorganism are performed without prior separation of the two or more microorganisms.

Kohne et al teaches a method for detecting, identifying, determining the state of growth and quantitating organisms (e.g.

bacteria or viruses) in biological samples (column 11 lines 47-48, column 4 lines 46-49, column 13 lines 10-15) by assessing the number of two or more microorganisms in the sample by analyzing the microorganisms' nucleic acid using probes specific for a particular genus or

and another for a different genus (column 12 lines 44-54) or using in lieu of a single probe a multiplicity or battery of different probes wherein each probe is complementary only to the R-RNA or T-RNA of a specific group of organisms and each probe is specific for a different group or organisms, wherein said method is performed without prior separation of the microorganisms. See column 13 lines 34-65 and column 14 lines 35-67 and column 52 claim 20-28. Kohne et al teaches a marker on the probe (labeled probe, column 20 line 46 and column 25 lines 57-60) and teaches an illustrative example of a radioactive probe, (see column 25lines 40-47, and lines 42-43). The process of hybridization of organisms' nucleic acid with the known probe sequence is a method of comparing at least a part of the microorganism's genome with a known probe sequence.

Kohne et al teaches that the detection, identifying and quantitation method can be used to determine the sensitivity of particular groups of organisms including viruses to antimicrobial agents including antiviral agents. See abstract and column 42 lines 6-41 and column 45 lines 45-62.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to use the hybridization method of Kohne et al to identify two or more different microorganisms in the biological samples of Peck et al and assess the numbers of two or more different microorganisms in said sample after incubation of the samples with antimicrobial(s) by using the hybridization method of Kohne et al, with a reasonable expectation of success because, Kohne et al teaches that said hybridization method can detect, identify and quantitate two or more different microorganisms in a sample without prior separation and can be used to determine the sensitivity of particular groups of organisms to antimicrobial agents. Said method of Kohne et al would have been desirable to one of ordinary skill in the art since different organisms can be identified in one sample and all can be tested for antimicrobial sensitivity which will make it faster for the physician to identify different microbial infections in a patient and determine which antimicrobial agent will treat the microbial infections (i.e. a comparison of the identification step and the step of determining in parallel the effect of antimicrobial on the two or more different microorganisms) so as to determine which antimicrobial to be used for treatment (i.e. corresponding to claim 12 and claim 13). See Peck et al (column 1) teaching the rapid need for physicians and patients to identify the pathogens in a patient afflicted with severe microbial infections and determine antimicrobial susceptibility so as to determine which antimicrobial to be used for treatment.

12. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998 cited previously and Kohne et al. US 5,738,988 April. 14, 1998 cited previously as applied to claims 1-3, 8-9 and 12-18 above, further in view of Grondhal et al. Journal of Clinical Microbiology, Jan. 1999, p. 1-7.

The combination of Peck et al and Kohne et al is set forth supra. Said combination does not teach that the identification of two or more different microorganisms as in step a involves amplification of nucleic acid from the microorganism.

Grondhal et al teaches the identification of two or more different microorganisms in a sample without prior separation using multiplex-reverse transcription PCR (mRT-PCR). Said mRT-PCR involves amplification of nucleic acid from the microorganism using primers specific to each of the different microorganisms of interest and analysis of the microorganism cDNA. See

p. 1 under title and abstract, p. 2 under materials and methods. Grondhal et al teaches that the simultaneous detection of different pathogens overcomes the limitations of single pathogen detection which is limited by inability to establish a specific etiology whenever the results is negative and by the inability to document simultaneous infections involving more than one infectious organism.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made that other methods known in the art such as a multiplex RT-PCR , that are also useful for the identification of more two or more different pathogens in a biological sample can be used to identify pathogens in the method of Peck et al and Kohne et al as combined, resulting in the instant invention with a reasonable expectation of success. One of skill in the art would have substituted the two methods of identifying more than one different pathogens, because both methods of identification accomplish simultaneous identification of two or more different pathogens in a sample (Simple substitution of one known element for another to obtain predictable results -see rationales for prima facie case of obviousness in *KSR International Co. v. Teleflex Inc.,* 550 U.S. ___,___, 82 USPQ2d 1385, 1395-97 (2007).

Furthermore, Grondhal et al teaches that the simultaneous detection of different pathogens overcomes the limitations of single pathogen detection which is limited by inability to establish a specific etiology whenever the results is negative and by the inability to document simultaneous infections involving more than one infectious organism and that m-RT-PCR can overcome this limitation.

13. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998 cited previously and Kohne et al. US 5,738,988 April. 14, 1998 cited previously as applied to claims 1-3, 8-9 and 12-18 above, further in view of Van Elden et al. The Journal of Clinical Microbiology, Jan. 2001, p. 196-200.

The combination of Peck et al and Kohne et al is set forth supra. Said combination does not teach that the identification of two or more different microorganisms as in step a and/or determining in parallel the effect one or more antimicrobials on the two or more different microorganisms as in step b involves amplification of nucleic acid from the microorganism , wherein the nucleic acid amplification uses the polymerase chain reaction, wherein the microorganisms DNA is analyzed.

Van Elden et al teaches the simultaneous identification and quantitation of two different microorganisms using multiplex quantitative Real-time PCR. See p. 196 title and abstract and column 2. Said multiplex real time PCR identifies two or more different microorganisms by analysis of each microorganism's nucleic acid without prior separation of the two or more different microorganisms. See title, abstract, p. 1197 under "real-time quantitative PCR" and table 2 p. 198.. Said method also assesses the number of each microorganism by analyzing the nucleic acid of each microorganism by said multiplex real time PCR. See p. 199 fig. 2. Said multiplex PCR uses primers specific to each different microorganism (see p. 197 table 1) and involves the analysis of the DNA (cDNA). Van Elden et al teaches that rapid highly sensitive and specific quantitative real-time PCR for the simultaneous detection of two different microorganism can be obtained within a few hours and allows time for adequate clinical management and the evaluation of antimicrobial therapy (in the instant case, antiviral therapy). See p. 200 column 1 last paragraph.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made that other nucleic acid analysis methods known in the art such as a multiplex quantitative real time PCR also useful for the identification and/or quantitation of two (or more) different pathogens in a biological sample and can be used as a substitute to identify and/or quantify each of the pathogens in the sample of Peck et al and Kohne et al as combined, resulting in the instant invention with a reasonable expectation of success. One of skill in the art would have substituted the two methods of identifying and/or quantifying each one of the different pathogens of Peck et al and Kohne et al, because both methods accomplish identification and/or quantification of more than one different pathogens in one sample. (Simple substitution of one known element for another to obtain predictable results -see rationales for prima facie case of obviousness in *KSR International Co. v. Teleflex Inc.,* 550 U.S. ___,___, 82 USPQ2d 1385, 1395-97 (2007).

Furthermore, Van Elden et al teaches the advantages of multiplex quantitative real-time PCR in that results can be obtained within a few hours and allows time for adequate clinical management and the evaluation of antimicrobial therapy.

14. Claim 7, 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peck et al. US 5,789,173 Aug. 4 1998 cited previously and Kohne et al. US 5,738,988 April. 14, 1998 cited previously as applied to claims 1-3, 8-9 and 12-18 above, further in view of De Baere et al. BMC Microbiology March 2, 2002, 2:4 (p. 1- p.12) cited in IDS.

The rejection of claim 9 again is addressing the alternative limitation in the claim i.e. rDNA, as claim 9 is dependent on claim 7 or claim 8.

The combination of Peck et al and Kohne et al is set forth supra. Said combination does not teach that analysis of the microorganism's nucleic acid comprises amplified rDNA analysis.

De Baere et al teaches analysis of more than one microorganism's nucleic acid in a sample comprising different microorganisms (different species) using amplified rDNA analysis (ARDRA) which allows for the identification of all the different microorganisms species at once and teaches that ARDRA can be followed by assessment of the antibiotic susceptibility of the strains. See p. 1 abstract. De Baere et al teaches that said method allows for the identification of most clinically important mycobacteria by comparison of the obtained profiles with a library of ARDA profiles obtained for reference strains. See p. 2 column 1 2nd full paragraph. See materials and methods p. 8 and p. 10. De Baere et al teaches that ARDRA allows for the identification of all the different microorganisms species at once and is non-demanding and can be carried out by a research laboratory technician. See p. 6 column 1 1st full paragraph

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to have used other methods of analyzing or identifying a microorganisms nucleic acid in the method of Peck et al and Kohne et al as combined, such as ARDRA, resulting in the instant invention with a reasonable expectation of success. One of skill in the art at the time the instant invention was made would have been motivated to use ARDRA because De Baere et al teaches analysis of more than one microorganism's nucleic acid in a sample comprising different microorganisms (different species) can be accomplished using amplified rDNA analysis (ARDRA) which allows for the identification of all the different microorganisms species at once and is non-demanding and can be carried out by a research laboratory technician.

Status of Claims

Claims 1-9 and 12-19 are rejected. No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645